recommendations. Its Dutch counterpart, ZI, issued only 8% of negative decisions to TCTs. The mode for a success rate in the Netherlands was special policy that enabled reimbursement of TCTs without CEA.

PCN251
THE CANCER DRUGS FUND: A SYSTEMATIC ANALYSIS OF THE REQUIREMENTS FOR INCLUSION ON THE ENGLISH NATIONAL LIST OF DRUGS FOR PRIORITY FUNDING
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OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access therapies that are not routinely available on the National Health Service (NHS). In April 2013, NHS England became responsible for the management of the CDF with a single national list of drugs for prioritised funding. As the CDF has recently been extended to 2016, it is increasingly important to understand the key criteria for inclusion on the CDF-approved list, which this research aims to define. **METHODS:** CDF appraisal reports were sourced from the NHS England website (April 2013 – March 2014) and the date, decision, and key rationale were extracted. **RESULTS:** 56 CDF decision summaries were available, 14 (25%) received full approval, 10 (18%) received conditional/restricted approval, 28 (50%) were rejected, and 4 (7%) were referred to commissioning. The key clinical attributes of each oncologic were given a numerical scoring that sum to a possible maximum +21 and minimum -4. The maximum score of any drug appraised was +8 and the minimum was -1. Excluding appraisals referred to commissioning, 16/18 appraisals scoring <2 were rejected (89%) compared to only 5/25 (20%) scoring >=2 (4/5 primarily due to trial comparator choice). 9 were not scored due to a lack of appropriate evidence. 11 submissions were only based on Phase II data (for such submissions, efficacy scores were halved), 5 of which were approved. **CONCLUSIONS:** A score of >=2 seems to be the key clinical threshold above which most drugs are CDF-approved, below which most are rejected. Given that 43/47 scoring drugs scored -1 for toxicity, this means that 3 points are typically required, which can come through a 4-5 month Progression Free Survival or Overall Survival gain (or a 2-3 month gain in both), but this must be versus the clinically relevant comparator.

PCN252
TESTING THE UTILITY OF THE NHS'S SYSTEMIC ANTI-CANCER THERAPY DATA SET FOR MULTI-INDICATION PRICING
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OBJECTIVES: The price of a medicine should reflect the value it offers to patients, the health care system and society more broadly. However, with current pricing manufacturers can only set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as being as 'too high' in certain indications. This apparent mismatch in value and cost can lead to patients being denied access to medicine in certain indications. **METHODS:** The implementation of a pricing model where there is differentiated value of a medicine across indications, line of therapy or if used as a mono/combination therapy requires the use of real world drug utilisation data. The Personalised Reimbursement Models project is at the forefront of the development and implementation of innovative pricing approaches in the UK. This project includes identifying and developing the infrastructure required in order to introduce Multi-Indication Pricing (MIP) into the NHS in the UK. We have worked alongside NHS Trusts and national bodies in a joint working project to validate and test the utility of the Systemic Anti-Cancer Therapy (SACT) dataset. **RESULTS:** This joint working project demonstrates that SACT has the potential to allow implementation of MIP in England. **CONCLUSIONS:** Following completion of this work we hope SACT will be used to introduce MIP in England - this will eliminate the administrative pharmacy burden of data collection for commercial schemes for cancer medicines, enabling medicines to be priced for the value they provide in each of their uses and ensure that patients are not disadvantaged due to having a condition potentially treatable by a product with multiple indications.

PCN253
ONCOLOGY PRODUCTS IN THE AMNOG PROCESS – LEARNINGS FOR A SUCCESSFUL DOSSIER SUBMISSION
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OBJECTIVES: Since AMNOG reform has taken effect 3.5 years ago, 78 dossiers have been evaluated by the G-BA. Especially with oncology agents, 28 products have started the process and G-BA has finalized decisions for 25 dossiers. In 20 cases additional benefit was granted. Therefore, the success rate of oncology products is 80% and much higher than the success rate of non-oncology products (29%). **METHODS:** An analysis of all oncology assessments will reveal key drivers responsible for the positive assessments by IQWiG and G-BA. Beside the study design (H2H vs. indirect comparison), and comparator choice the analysis will focus on submitted endpoints. It will be evaluated which endpoints contribute most in oncology indications to additional benefit. **RESULTS:** Additional benefit is assessed based on patient relevant endpoints (mortality, morbidity, quality of life & safety). More than 55% of submitted endpoints fall in the safety category, followed by morbidity (approx. 30%), mortality (approx. 10%) and quality of life (approx. 5%). The most important endpoint is mortality (OS), where the G-BA granted additional benefit in 18 out of 20 dossiers primarily based on OS data. In terms of morbidity, PFS, ORR and "Time to Pain Progression" are the top three most submitted morbidity endpoints; however, only "Time to Pain Progression" led to additional benefit in 2 out of 3 cases. Only in one case quality of life contributed to the overall additional benefit decision. **CONCLUSIONS:** OS will continue to be the most additional benefit contributing endpoint in oncology. In the absence of OS, PFS will not help in the overall additional benefit decision by G-BA, unless the MNF can justify PSF to be patient relevant according to IQWiG methodology. Although QoL is an accepted endpoint by G-BA, due to the high methodological standards set by G-BA and IQWiG, manufacturers should de-prioritize this endpoint.

PCN254
MEDIA COVERAGE OF THE NICE FIRST DRAFT CONSULTATION GUIDANCE FOR TRASTUZUMAB EMANTANSINE (KADCYLA) IN BREAST CANCER
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OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criterion. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncologics), perhaps the most memorable example of which relates to the funding of Herceptin in early-stage breast cancer in 2005. This research aimed to evaluate how the media currently report NICE decision-making, focussing on the NICE appraisal consultation document not recommending Kadcyla on 23rdApril 2014 with a cost per Quality Added Life Year (QALY) >£180,000, far exceeding typical NICE approval thresholds (~£30,000/QALY). **METHODS:** A selection of national and regional newspaper websites, UK broadcasters, press agencies, pharmaceutical trade and medical publications were screened for any articles published between 23rd-25thApril 2014 regarding this NICE draft guidance from which key criteria were extracted and compared. **RESULTS:** 19 articles were extracted (6 national newspapers, 6 regional newspapers, 3 broadcasters, and 4 other). 7/19 articles primarily focussed on the reaction of a patient/doctor, all of whom were particularly critical of the NICE decision. 3/19 focussed on the high proposed cost of the new drug, 2 of which were critical of the pharmaceutical company. 9/19 followed the format of briefly summarising the decision and drug, with the majority of the article comprising reactions from various sources. However, there was an overall numerically higher number of sources in each article criticizing NICE (38, mean 2.0 per article) than those defending the NICE decision (21, mean 1.1 per article). **CONCLUSIONS:** NICE decisions not to fund oncology drugs still seem to be predominantly faced by a hostile media reception that focus more on patient reactions than the difficulties of how to allocate finite health care resources to best optimise care in the NHS.

PCN255
COMPARING HOW SINGLE ARM PHASE II TRIAL DATA CAN SUPPORT APPROVAL OF ONCOLOGICS BY EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODIES
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OBJECTIVES: The European Medicines Agency (EMA) approved 15 oncologics across 24 indications based on pivotal single-arm Phase II data (Macaulay, ISPOR Dublin 2013). Approval was typically granted for indications in which there was no therapeutic alternative where a response rate of ≥35% was demonstrated. This research aims to compare how such data can further support approval between different European Health Technology Agencies (HTAs). **METHODS:** Relevant National Institute of Health and Care Excellence (NICE), Scottish Medicines Commission (SMC), Commission de la Transparence (CT), Institute for Quality and Efficiency in Health Care (IQWiG), Federal Joint Committee (G-BA), and Swedish Dental and Pharmaceutical Benefits Agency (TLV) reports were sourced for any oncologic approved by the EMA on the basis of pivotal Phase II data (up to March 2014) and the decision and key rationale were analysed. **RESULTS:** CT fully reimbursed 14/14 (100%) oncologics appraised on the basis of pivotal Phase II data, with 10/14 obtaining ASMRs I-III. In Germany (IQWiG), 6/6 (100%) oncologics appraised on this basis were deemed to offer some added benefit, avoiding reference pricing (5/6 were orphan drugs which are not subject to a benefit assessment). NICE approved 5/7 (71%), SMC 6/11 (55%), and TLV 7/7 (100%) of oncologics appraised on Phase II data. For NICE/SMC/TLV rejected drugs, the clinical case was not strongly criticised, rather cost-utility values were deemed too high and uncertain. Even for approved drugs, the lack of comparative data was critiqued as introducing considerable uncertainty to submissions. **CONCLUSIONS:** For any oncologic approved by the EMA on the basis of Phase II data, favourable ASMR and benefit ratings can be awarded on this basis by the CT and IQWiG/G-BA, respectively. NICE, SMC, and TLV recommendations are conditional on cost-effectiveness being adequately demonstrated with additional price discounts required to offset inherent uncertainties in cost-utility modelling from such limited clinical data.

PCN256
COMPARING ACCESS TO DRUGS THROUGH THE CDF AND BY NICE – THE CDF STIPULATE STRICTER CLINICAL CRITERIA BUT WILL ALSO APPROVE FUNDING FOR OFF-LABEL USAGE
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OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable cancer patients to gain access to therapies that are not routinely available on the NHS. However, this fund has been criticised for providing funding for therapies that have not been shown to be cost-effective by the National Institute for Health and Care Excellence (NICE). This research aims to define how restrictive criteria are for accessing drugs under the CDF and how this compares to access under NICE. **METHODS:** A systematic review of the criteria for accessing drugs according to the national CDF list was undertaken and was compared to NICE-published statistics for oncology technology appraisals up to 31st March 2014. **RESULTS:** 80 oncologic indications have been approved under the CDF, each with specific criteria for access and usage. Overall, an average of 5.0 (range 3-11) criteria were specified for each drug. Typically, 3 criteria were specified for all drugs: 1) consultant specialist prescriber; 2) specifying the disease; and 3) the line of therapy. However, many agents had additional restrictions on top of this, including 20/80 (25%) specifying the performance status (14 had 0-1; 6 had 0-2) and 12/80 (15%) to be used within the treating Trust's governance framework as these drugs were not licensed in the specified indication.